04-13-05

Attorney Docket No.: 28142-501 UTII

(formerly 59533(49397

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Pace and Smith

CONFIRMATION NO.:

7151

U.S. SERIAL NO.

10/661,458

CUSTOMER NO.:

35437

FILED

September 10, 2003

TC/A.U.

1614

EXAMINER

Not Yet Assigned

For

Methods and Compositions for Reducing the Risk Associated With

the Administration of Opioid Analgesics in Patients With Diagnosed or

Undiagnosed Respiratory Illness

Mail Stop Amendment

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

EXPRESS MAIL TRANSMITTAL

Date of Deposit: April 11, 2005

I hereby certify that the document(s) and/or fee(s) listed below are being deposited with the United States Patent and Trademark Office as Express Mail bearing Express Mail Label No. EV 399525075 US under 37 C.F.R. §1.10 in an envelope with prepaid postage on the date indicated above and addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450:

- 1. Supplemental Information Disclosure Statement (2 pages), in duplicate;
- 2. Modified Form 1449/PTO (1 page), in duplicate;
- 3. Cited References A5-A6, B1, and C7-C9;
- Express Mail Transmittal (1 page), in duplicate; and 4.
- 5. Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room is respectfully requested to contact the undersigned collect at (212) 935-3000, New York, New York. The Director is authorized to charge any deficiencies to Deposit Account No. 50-0311, Reference No. 28142-501 UTIL, Customer No. 35437.

Dated: April 11, 2005

Leslie A. Serunian, Reg. No. 35,353

c/o MINTZ LEVIN COHEN FERRIS

GLOVSKY & POPEO, P.C.

The Chrysler Center

666 Third Avenue, 24th Floor

New York, NY 10017

Telephone: (212) 935-3000 Facsimile: (212) 983-3115

Express Mail Label No.: EV399525075US

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SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the references cited.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action on the merits for the above-identified application. Accordingly, no fee or certification is believed to be required.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims. It is also respectfully requested that the Examiner initial, sign and date, and return a copy of the signed modified Form PTO-1449 with the next U.S. PTO communication, to evidence that the cited information has been fully considered by the U.S. Patent and Trademark Office during the examination of this application.

By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the

Applicants: Pace and Smith
U.S.S.N.: 10/661,458

Attorney Docket No.: 28142-501 UTIL
(formerly 59533(49397))

information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

The order of presentation of the references should not be construed as an indication of the importance of the references. The Examiner is urged to form his/her own conclusion regarding the relevance of the cited information.

Please charge any fees that may be due to Deposit Account No. 50-0311, Reference No. 28142-501 UTIL, Customer No. 35437.

Respectfully submitted,

Leslie A. Serunian, Reg. No. 35,353 c/o MINTZ, LEVIN, COHN, FERRIS GLOVSKY & POPEO P.C.

The Chrysler Center

666 Third Avenue, 24th Floor New York, New York 10017

Tel: (212) 935-3000 Fax: (212) 983-3115

Dated: April 11, 2005

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PTO/SB (12-97)

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Modified Form 1449/PTO 10/661,458 **Application Number SUPPLEMENTAL** Filing Date 09/10/03 INFORMATION DISCLOSURE First Named Inventor Pace 1614 STATEMENT BY APPLICANT Group Art Unit **Examiner Name** Not Yet Assigned (use as many sheets as necessary) 28142-501 **Attorney Docket Number**

U.S. PATENT DOCUMENTS							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date
	A5	5,317,022	05/31/94	Borsodi et al.			02/03/92
	A6	5,457,110	10/10/95	Borsodi et al.			05/19/94

				FOREIGN PATENT DOCUMENTS	- Samuel	
Exam Initials	Cite No.	Foreig Office	n Patent Document Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
	B1	AU	706 691 B	University of Queensland; Lynx Project Limited	May 7, 1997	x

NON PATENT LITERATURE DOCUMENTS			
Exam Initials			
	C7	Korttila and Hovorka (1987). Acta Anaesthesiologica Scandinavica 31: 673-679.	
	C8 Wilson P. (2004). Seminars in Pain Medicine 2: 228-232.		
	C9	International Search Report for PCT/US2004/029731 mailed February 15, 2005.	

*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. , filed _, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

kaminer gnature	Date Considered	
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

NYC 319964v1